AMENDED IN SENATE JULY 6, 2009

AMENDED IN ASSEMBLY APRIL 23, 2009

AMENDED IN ASSEMBLY APRIL 1, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 830

Introduced by Assembly Member Cook
(Principal coauthor: Assembly Member Krekorian)

February 26, 2009

~~An act to amend Sections 13, 4025, 4053, and 4342 of the Business and Professions Code, to amend Sections 1367.21, 1370.4, 11014, 109920, 109985, 111225, 111235, 111656.4, and 150204 of the Health~~ *An act to amend Sections 1367.21 and 1370.4 of the Health* and Safety Code, to amend Sections 10123.195 and 10145.3 of the ~~Insurance Code, to amend Section 383 of the Penal Code, to amend Section 47121 of the Public Resources Code, and to amend Sections~~ *Insurance Code, and to amend Sections* 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 830, as amended, Cook. Drugs and devices.

Existing law references various drug compendiums and compendia, including the United States Pharmacopoeia, ~~in various licensure, health care, and social services provisions~~ *for purposes of the Knox-Keene Health Care Service Plan Act of 1975, disability insurance, and for Medi-Cal*.

This bill would replace these references with ~~a compendium approved by the federal Centers for Medicare and Medicaid Services~~ *references*

to a specified compendia, as approved by the federal Centers for Medicare and Medicaid Services.

~~Existing law makes it a crime to knowingly sell, or keep or offer for sale, or otherwise dispose of any drug or medicine, knowing that it is adulterated. A drug is deemed to be adulterated based upon the standard of strength, quality, or purity in the United States Pharmacopoeia.~~

~~This bill would replace the above drug compendium's with a compendium approved by the federal Centers for Medicare and Medicaid Services. By changing the definition of a crime, this bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

~~SECTION 1. Section 13 of the Business and Professions Code is amended to read:~~

~~13. The term "materia medica" as used in this code or in any initiative act referred to in this code, means those substances listed in a compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services, except substances covered by subdivision (a) of Section 4052 and Section 4057.~~

~~SEC. 2. Section 4025 of the Business and Professions Code is amended to read:~~

~~4025. "Drug" means any of the following:~~

~~(a) Articles recognized in a compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.~~

~~(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.~~

~~(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.~~

~~(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).~~

~~SEC. 3. Section 4053 of the Business and Professions Code is amended to read:~~

~~4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.~~

~~(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:~~

~~(1) He or she shall be a high school graduate or possess a general education development equivalent.~~

~~(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.~~

~~(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:~~

~~(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.~~

~~(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.~~

~~(C) Knowledge and understanding of quality control systems.~~

~~(D) Knowledge and understanding of the standards relating to the safe storage and handling of drugs in a compendium approved by the federal Centers for Medicare and Medicaid Services.~~

~~(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.~~

~~(4) The board may, by regulation, require training programs to include additional material.~~

~~(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.~~

~~(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.~~

~~(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.~~

~~(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).~~

~~SEC. 4. Section 4342 of the Business and Professions Code is amended to read:~~

~~4342. (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of a compendium approved by the federal Centers for Medicare and Medicaid Services or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).~~

~~(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.~~

~~SEC. 5.~~

SECTION 1. Section 1367.21 of the Health and Safety Code is amended to read:

1367.21. (a) No health care service plan contract which covers prescription drug benefits shall be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not

on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition ~~by either of the following:~~

~~(A) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~ *by one of the following compendia, as approved by the federal Centers for Medicare and Medicaid Services:*

(A) The American Hospital Formulary Service's Drug Information.

(B) The Elsevier Gold Standard's Clinical Pharmacology.

(C) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(D) The Thomson Micromedex DrugDex.

~~(B)~~

(E) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(h) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

(i) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

~~SEC. 6.~~

SEC. 2. Section 1370.4 of the Health and Safety Code is amended to read:

1370.4. (a) Every health care service plan shall provide an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual enrollees who meet all of the following criteria:

(1) (A) The enrollee has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device,

procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that are not otherwise covered pursuant to the plan contact.

(4) The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3).

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(b) The plan's decision to delay, deny, or modify experimental or investigational therapies shall be subject to the independent medical review process under Article 5.55 (commencing with Section 1374.30) except that, in lieu of the information specified in subdivision (b) of Section 1374.33, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall

be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 1374.33.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database *of* Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

~~(4) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~

(4) The following standard reference compendia, as approved by the federal Centers for Medicare and Medicaid Services: the American Hospital Formulary Service's Drug Information, the American Dental Association Accepted Dental Therapeutics, the Elsevier Gold Standard's Clinical Pharmacology, the National

Comprehensive Cancer Network Drug and Biologics Compendium, and the Thomson Micromedex DrugDex.

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(6) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

~~SEC. 7. Section 11014 of the Health and Safety Code is amended to read:~~

~~11014. "Drug" means (a) substances recognized as drugs in a compendium approved by the federal Centers for Medicare and Medicaid Services; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (d) substances intended for use as a component of any article specified in subdivision (a), (b), or (c) of this section. It does not include devices or their components, parts, or accessories.~~

~~SEC. 8. Section 109920 of the Health and Safety Code is amended to read:~~

~~109920. "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:~~

~~(a) Recognized in a compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.~~

~~(b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.~~

~~(c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of~~

~~its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.~~

~~SEC. 9. Section 109985 of the Health and Safety Code is amended to read:~~

~~109985. "Official compendium" means a compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.~~

~~SEC. 10. Section 111225 of the Health and Safety Code is amended to read:~~

~~111225. As used in this chapter, with respect to a drug or drug ingredient, "established name" means either of the following:~~

~~(a) The name designated pursuant to Section 508 of the federal act (21 U.S.C. Sec. 358).~~

~~(b) If there is no designated name and the drug or ingredient is an article recognized in a compendium approved by the federal Centers for Medicare and Medicaid Services, then the official title in the compendia is the established name.~~

~~If neither subdivision (a) or (b) of this section applies, the common or usual name, if any, of the drug or of the ingredient is the established name. When an article is recognized in a compendium approved by the federal Centers for Medicare and Medicaid Services and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the approved compendium shall apply unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, the official title used in the Homeopathic Pharmacopoeia shall apply.~~

~~SEC. 11. Section 111235 of the Health and Safety Code is amended to read:~~

~~111235. Whenever a drug is recognized in both a compendium approved by the federal Centers for Medicare and Medicaid Services and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the approved compendium unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, it shall be subject to the Homeopathic Pharmacopoeia of the United States and not to those of the approved compendium.~~

~~SEC. 12. Section 111656.4 of the Health and Safety Code is amended to read:~~

~~111656.4. Section 4051 of the Business and Professions Code shall not prohibit a home medical device retail facility from selling or dispensing prescription devices if the department finds that sufficient qualified supervision is employed by the home medical device retail facility to adequately safeguard and protect the public health. Each person applying to the department for this exemption shall meet the following requirements to obtain and maintain the exemption:~~

~~(a) A licensed pharmacist or an exemptee who meets the requirements set forth in paragraphs (1) to (5), inclusive, and whose license of exemption is currently valid, shall be in charge of the home medical device retail facility.~~

~~(1) He or she shall be a high school graduate or possess a general education development equivalent.~~

~~(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices.~~

~~(3) He or she shall complete a training program that addresses each of the following subjects that are applicable to his or her duties:~~

~~(A) Knowledge and understanding of state and federal laws relating to the distribution of dangerous drugs and dangerous devices.~~

~~(B) Knowledge and understanding of state and federal laws relating the distribution of controlled substances.~~

~~(C) Knowledge and understanding of quality control systems.~~

~~(D) Knowledge and understanding of the standards relating to the safe storage and handling of drugs in a compendium approved by the federal Centers for Medicare and Medicaid Services.~~

~~(E) Knowledge and understanding relating to the safe storage and handling of home medical devices.~~

~~(F) Knowledge and understanding of prescription terminology, abbreviations, and format.~~

~~(4) The department may, by regulation, require training programs that include additional material.~~

~~(5) The department shall not issue an exemptee a license until the applicant provides proof of completion of the required training~~

~~that the department determines is adequate to fulfill these requirements.~~

~~(b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.~~

~~(c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.~~

~~(d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.~~

~~(e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device retail facility for emergency or after hours service to patients having prescriptions for prescription devices.~~

~~(f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a prescription device has been delivered from the locked storage to a patient.~~

~~SEC. 13. Section 150204 of the Health and Safety Code is amended to read:~~

~~150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county~~

~~pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.~~

~~(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:~~

~~(1) Establishing eligibility for medically indigent patients who may participate in the program.~~

~~(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.~~

~~(3) Developing a formulary of medications appropriate for the repository and distribution program.~~

~~(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.~~

~~(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.~~

~~(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:~~

~~(1) The medication shall not be a controlled substance.~~

~~(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by a compendium approved by the federal Centers for Medicare and Medicaid Services or the product manufacturer.~~

~~(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.~~

~~(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet standards in a compendium approved by the federal Centers for Medicare and Medicaid Services is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.~~

~~(e) A pharmacist shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.~~

~~(f) A pharmacist shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.~~

~~(g) Medication that is donated to the repository and distribution program shall be handled in any of the following ways:~~

~~(1) Dispensed to an eligible patient.~~

~~(2) Destroyed.~~

~~(3) Returned to a reverse distributor.~~

~~(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.~~

~~(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.~~

~~(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.~~

~~(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.~~

~~(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.~~

~~(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include~~

~~specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with standards in a compendium approved by the federal Centers for Medicare and Medicaid Services and the Pharmacy Law.~~

~~(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.~~

~~SEC. 14.~~

SEC. 3. Section 10123.195 of the Insurance Code is amended to read:

10123.195. (a) No group or individual disability insurance policy issued, delivered, or renewed in this state or certificate of group disability insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state that, as a provision of hospital, medical, or surgical services, directly or indirectly covers prescription drugs shall limit or exclude coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the insurer's formulary, if any.

(3) The drug has been recognized for treatment of that condition ~~by either of the following:~~

~~(A) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~ *by one of the following compendia, as approved by the federal Centers for Medicare and Medicaid Services:*

(A) The American Hospital Formulary Service's Drug Information.

(B) The Elsevier Gold Standard's Clinical Pharmacology.

(C) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(D) The Thomson Micromedex DrugDex.

~~(B)~~

(E) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

(g) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is located outside of California.

(h) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(i) If an insurer denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision

is subject to review under the Independent Medical Review System of Article 3.5 (commencing with Section 10169).

(j) This section is not applicable to vision-only, dental-only, Medicare or Champus supplement, disability income, long-term care, accident-only, specified disease or hospital confinement indemnity insurance.

~~SEC. 15.~~

SEC. 4. Section 10145.3 of the Insurance Code is amended to read:

10145.3. (a) Every disability insurer that covers hospital, medical, or surgical benefits shall provide an external, independent review process to examine the insurer's coverage decisions regarding experimental or investigational therapies for individual insureds who meet all of the following criteria:

(1) (A) The insured has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The insured's physician certifies that the insured has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the insured, for which standard therapies would not be medically appropriate for the insured, or for which there is no more beneficial standard therapy covered by the insurer than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies, or (B) the insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more

beneficial for the insured than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the insurer to pay for the services of a noncontracting physician, provided pursuant to this subdivision, that are not otherwise covered pursuant to the contract.

(4) The insured has been denied coverage by the insurer for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3), unless coverage for the specific therapy has been excluded by the insurer's contract.

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service except for the insurer's determination that the therapy is experimental or under investigation.

(b) The insurer's decision to deny, delay, or modify experimental or investigational therapies shall be subject to the independent medical review process established under Article 3.5 (commencing with Section 10169) of Chapter 1 of Part 2 of Division 2, except that in lieu of the information specified in subdivision (b) of Section 10169.3, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The insurer shall notify eligible insureds in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the insured's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 10169.3.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is

not likely to be more beneficial for the insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing the insured's specific medical condition, the relevant documents, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS database *of* Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

~~(4) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~

(4) The following standard reference compendia, as approved by the federal Centers for Medicare and Medicaid Services: the American Hospital Formulary Service's Drug Information, the American Dental Association Accepted Dental Therapeutics, the Elsevier Gold Standard's Clinical Pharmacology, the National Comprehensive Cancer Network Drug and Biologics Compendium, and the Thomson Micromedex DrugDex.

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care

Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(6) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

~~SEC. 16. Section 383 of the Penal Code is amended to read:~~

~~383. Every person who knowingly sells, or keeps or offers for sale, or otherwise disposes of any article of food, drink, drug, or medicine, knowing that the same is adulterated or has become tainted, decayed, spoiled, or otherwise unwholesome or unfit to be eaten or drunk, with intent to permit the same to be eaten or drunk, is guilty of a misdemeanor, and must be fined not exceeding one thousand dollars ($1,000), or imprisoned in the county jail not exceeding six months, or both, and may, in the discretion of the court, be adjudged to pay, in addition, all the necessary expenses, not exceeding one thousand dollars ($1,000), incurred in inspecting and analyzing these articles. The term "drug," as used herein, includes all medicines for internal or external use, antiseptics, disinfectants, and cosmetics. The term "food," as used herein, includes all articles used for food or drink by man, whether simple, mixed, or compound. Any article is deemed to be adulterated within the meaning of this section:~~

~~(a) In case of drugs: (1) if, when sold under or by a name recognized in a compendium approved by the federal Centers of Medicare and Medicaid Services, it differs materially from the standard of strength, quality, or purity laid down therein; (2) if, when sold under or by a name not recognized in a compendium approved by the federal Centers of Medicare and Medicaid Services, but which is found in some other pharmacopoeia or other standard work on materia medica, it differs materially from the standard of strength, quality, or purity laid down in such work; (3) if its strength, quality, or purity falls below the professed standard under which it is sold.~~

~~(b) In the case of food: (1) if any substance or substances have been mixed with it, so as to lower or depreciate, or injuriously affect its quality, strength, or purity; (2) if any inferior or cheaper substance or substances have been substituted wholly or in part~~

~~for it; (3) if any valuable or necessary constituent or ingredient has been wholly or in part abstracted from it; (4) if it is an imitation of, or is sold under the name of, another article; (5) if it consists wholly, or in part, of a diseased, decomposed, putrid, infected, tainted, or rotten animal or vegetable substance or article, whether manufactured or not; or in the case of milk, if it is the produce of a diseased animal; (6) if it is colored, coated, polished, or powdered, whereby damage or inferiority is concealed, or if by any means it is made to appear better or of greater value than it really is; (7) if it contains any added substance or ingredient which is poisonous or injurious to health.~~

~~SEC. 17. Section 47121 of the Public Resources Code is amended to read:~~

~~47121. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:~~

~~(a) "Consumer" means an individual purchaser or owner of a drug. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.~~

~~(b) "Drug" means any of the following:~~

~~(1) Articles recognized in a compendium or supplement thereof approved by the federal Centers for Medicare and Medicaid Services.~~

~~(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.~~

~~(3) Articles, excluding food, intended to affect the structure or function of the body of humans or other animals.~~

~~(4) Articles intended for use as a component of an article specified in paragraph (1), (2), or (3).~~

~~(c) "Participant" means any entity which the board deems appropriate for implementing and evaluating a model program and which chooses to participate, including, but not limited to, governmental entities, pharmacies, veterinarians, clinics, and other medical settings.~~

~~(d) "Sale" includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.~~

~~SEC. 18.~~

SEC. 5. Section 14105.43 of the Welfare and Institutions Code is amended to read:

14105.43. (a) (1) Notwithstanding other provisions of this chapter, any drug which is approved by the federal Food and Drug Administration for use in the treatment of acquired immunodeficiency syndrome (AIDS) or an AIDS-related condition shall be deemed to be approved for addition to the Medi-Cal list of contract drugs only for the purpose of treating AIDS or an AIDS-related condition, for the period prior to the completion of the procedures established pursuant to Section 14105.33.

(2) (A) In addition to any drug that is deemed to be approved pursuant to paragraph (1), any drug that meets any of the following criteria shall be a Medi-Cal benefit, subject to utilization controls:

(i) Any vaccine to protect against human immunodeficiency virus (HIV) infection.

(ii) Any antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with human immunodeficiency virus to counteract the effects of that infection.

(iii) Any drug or biologic used to treat opportunistic infections associated with acquired immune deficiency syndrome, that have been found to be medically accepted indications and that has either been approved by the federal Food and Drug Administration or ~~recognized for that use in either of the following:~~

~~(I) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~ *recognized for that use in one of the following compendia, as approved by the federal Centers for Medicare and Medicaid Services:*

(I) The American Hospital Formulary Service's Drug Information.

(II) The Elsevier Gold Standard's Clinical Pharmacology.

(III) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(IV) The Thomson Micromedex DrugDex.

~~(II)~~

(V) Two articles from peer reviewed medical journals that present data supporting the proposed use or uses as generally safe and effective.

(iv) Any drug or biologic used to treat the chemotherapy-induced suppression of the human immune system resulting from the treatment of acquired immune deficiency syndrome.

(3) The department shall add any drug deemed to be approved pursuant to paragraph (1) to the Medi-Cal list of contract drugs or allow the provision of the drug as a Medi-Cal benefit, subject to utilization controls, pursuant to paragraph (2), only if the manufacturer of the drug has executed a contract with the Centers for Medicare and Medicaid Services which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code.

(b) Any drug deemed to be approved pursuant to paragraph (1) of subdivision (a) shall be immediately added to the Medi-Cal list of contract drugs, and shall be exempt from the contract requirements of Section 14105.33.

(c) If it is determined pursuant to subdivision (c) of Section 14105.39 that a drug to which subdivision (a) applies should not be placed on the Medi-Cal list of contract drugs, that drug shall no longer be deemed to be approved for addition to the list of contract drugs pursuant to subdivision (a).

~~SEC. 19.~~

SEC. 6. Section 14133.2 of the Welfare and Institutions Code is amended to read:

14133.2. (a) The director shall include in the Medi-Cal list of contract drugs any drug approved for the treatment of cancer by the federal Food and Drug Administration, so long as the manufacturer has executed a contract with the Health Care Financing Administration which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code. These drugs shall be exempt from the contract requirements of Section 14105.33.

(b) In addition to any drug added to the list of contract drugs pursuant to subdivision (a), any drug that meets either of the following criteria and for which the manufacturer has executed a contract with the Health Care Financing Administration that provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code, shall be a Medi-Cal benefit, subject to utilization controls, unless the contract requirements of Section 14105.33 have been complied with:

(1) Any drug approved by the federal Food and Drug Administration for treatment of opportunistic infections associated with cancer.

(2) Any drug or biologic used in an anticancer chemotherapeutic regimen for a medically accepted indication, which has either been approved by the federal Food and Drug Administration, or ~~recognized for that use in either of the following:~~

~~(A) A compendium approved by the federal Centers for Medicare and Medicaid Services.~~ *recognized for that use in one of the following compendia, as approved by the federal Centers for Medicare and Medicaid Services:*

(A) The American Hospital Formulary Service's Drug Information.

(B) The Elsevier Gold Standard's Clinical Pharmacology.

(C) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(D) The Thomson Micromedex DrugDex.

~~(B)~~

(E) Two articles from peer reviewed medical journals that present data supporting the proposed use or uses as generally safe and effective.

~~SEC. 20. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

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